

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Status of all claims

1. Claim(s) 1, 3-9, 12-19 are pending and under consideration.
2. Claim(s) 2, 10 and 11 have been cancelled.

Support for claim amendments:

Support for a device that includes a plurality of stents where each of the stents has a proximal end and a distal end and includes a plurality of struts disposed circumferentially about the stent in a zig-zag pattern can be found, for example, at the top of page 7 beginning at line 3 of the originally-filed application, and in Figure 1. Support for each of the struts in the zig-zag pattern having a proximal end that converges with the proximal end of an adjacent strut at an eyelet occurring at the proximal end of the stent such that the stent provides a circumferential array of proximal eyelets about its proximal end, and for each of the struts in the zig-zag pattern further having a distal end that converges with the distal end of an adjacent strut at an eyelet occurring at the distal end of the stent such that the stent provides a circumferential array of distal eyelets about its distal end can be found, for example, in Figure 1 and on page 7 of the application. Support for adjacent stents connected together by a monofilament extending through adjacent eyelets of the adjacent stents and for a plurality of stents including a first stent and an adjacent, second stent connected together by a monofilament that extends through the proximal eyelets of the first stent and the distal eyelets of the second stent can be found, for

example, at the middle of page 4 beginning at line 14 of the originally-filed application. Support for the proximal eyelets of a first stent and the distal eyelets of an adjacent, second stent being offset from one another along the connecting monofilament is clearly seen in Figure 1. Support for securing the sleeve to inside and outside surface of the stents/frame by sutures through proximal eyelets and distal eyelets of each of the plurality of stents can be found, for example, at page 7, lines 7-9.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 3-9 and 12-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Babbs et al., U.S. Patent 6,475,232 in view of Myers et al., U.S. Patent 5,735,892 and further in view of Gianturco, U.S. Patent 5,282,824. Applicants respectfully traverse in light of the above amendments.

In addition to requiring a plurality of stents, all of the Applicant's claims now require that the covering be secured in a very specific and purposeful manner to the inside and outside surfaces of the stents/frame. In claim 1, for example, the securement now includes (a) suturing to struts of the stent; and (b) suturing through proximal and distal eyelets of each of the stents. None of the cited references remotely teach or suggest this specific attachment mode, much less the total combination of features recited in claim 1.

Under a proper §103 analysis, the question is not whether someone *could* have made the proposed modification. Instead, the correct question is whether one skilled in the art would have done so based on the actual teachings of the prior art. Here, it is clear that if we remove the hindsight bias of Applicant's own disclosure, the cited references

provide no hint or suggestion whatsoever to arrange the various components in the exact manners expressed in the claims.

The very specific and purposeful modes of securement recited in Applicant's claims provide exceptional mechanical results for a device having multiple stents and both an inside and an outside cover that is to become remodeled by host tissue. The suturing through proximal and distal eyelets of each of the individual stents helps fix the locations of the eyelets relative to each other in the overall device and relative to the inside and outside cover. Thus, with this type of attachment, the frame and the cover are able to provide each other with increased integrity, and to allow each other to move in a more controlled and durable fashion. As described at page 7, line 14 of the originally-filed application, suturing through the eyelets minimizes axial movement of the covering along the frame. This, in turn, helps to stabilize both the covering and the individual frame pieces at the implant site. By suturing through an eyelet, the positioning of that eyelet relative to the covering will generally be maintained. Thus, when the eyelets of adjacent stents are in an offset arrangement as claim in claim 3, for example, axially stable fixation of the eyelet-cover position will assist in preventing the eyelets of the adjacent stents from overlapping or crossing over one another, e.g., under torsional forces or rounding bends. Instead, the offset or staggered positioning of the eyelets (and adjoining strut structures) will be maintained.

Suturing to the struts, on the other hand, while also securing the covering to the stents, can be arranged to give a certain degree of flexibility to the frame-covering attachment between the eyelets. Thus, while both types of suturing work to secure the

covering to the stents/frame, they each offer their own advantages and contributions to the overall device.

With the claimed modes of attachment, a functional synergy is realized among the various components at the vascular implant site as the overall device is confronted with bending, twisting and other forces. The frame and covering are able to function in unison in a unique manner to withstand the various forces at the implant site, while also providing an optimal environment for remodeling to occur despite the harsh conditions.

It is not surprising that the cited references fail to teach or suggest any of these advantages or results since none of the references contemplated a device having multiple stents and both an inside and outside covering material that is to become remodeled by host tissue. Therefore, it is unclear why or how, absent hindsight, a person of ordinary skill in the art would have been led to conveniently pick and choose only so much as is necessary from the various references to construct the very specific and purposeful devices recited in Applicant's claims.

Accordingly, for any one of claims 1, 3-9 or 12-19, the combination of Babbs in view of Myers and further in view of Gianturco fails to teach each and every element of that claim, and therefore a *prima facie* case of obviousness has not been established with regard to any of these claims by these rejections. Their withdrawal is therefore solicited.

In light of the above amendment and remarks, maintenance of the present obviousness rejection would be improper. Withdrawal of this rejection and allowance of this application are therefore solicited.

Request for Interview

The Applicant requests an opportunity for an interview of the Examiner if the Examiner believes that any objection or rejection could be maintained against the application as amended. The Examiner is requested to contact the undersigned attorney to arrange any such interview necessary.

Respectfully submitted,

By



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